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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,566	02/15/2002	Brian Brockway	1155.1101101	3298

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Robert E. Atkinson
CROMPTON, SEAGER & TUFTE, LLC
Suite 895
331 Second Avenue South
Minneapolis, MN 55401-2246

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,566	BROCKWAY ET AL. <i>BN</i>	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 44, 48-52, 55 and 60-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 44, 48-52, 55 and 60-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3736

The examiner notes that the prior applications fail to provide support for the subject matter as is now claimed, and as such, the current claims only have a filing date of the current application, or 2/15/20002

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide support for the subject matter of claim 44, particular the in growth deterring surface and the specific positional relationship recited in the claim, i.e. that when the in growth surface is attached to the epicardium, the deterring surface faces the pericardium. Since this was in an original claim, it may be added to the specification, provided that no new matter is introduced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-12 , 50, 63, and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al 5,353,800. Pohndorf teaches a method of implanting a pressure measurement device in the heart of a patient comprising providing a pressure sensor assembly 10 including a pressure transducer 14 and a pressure transmission

Art Unit: 3736

catheter 16, where the catheter has a distal end portion having an opening with a barrier, i.e. a membrane (see column 4, lines 26-30). In addition, the pressure transducer is proximal to the distal end portion. The method further includes positioning the catheter across a heart wall, with the opening in chamber of the heart (see figure 3 and the associated discussion). Claim 3 is rejected in that the pressure measurement device is positioned with the catheter across all layers of the heart (see figure 3 and column 5, lines 1-32). Claims 4 and 6 are rejected in that the catheter can be positioned across the heart wall, i.e. the ventricular septum, with the opening in the left ventricle (see column 4, lines 57-69). Claim 5 is rejected in that the opening is in the right ventricle (see column 5, lines 1-11). Claim 7 is rejected in that in figure 7, there is further included a pressure transmitting catheter 462 and a coiled needle used to attach the device to the heart tissue. Claims 8 and 9 are rejected in that depending on where the device is used, the housing 14 may be secured inside or outside of the heart. Claims 10 and 11 are rejected in that the positioning step is done transluminally, which is surgically. With respect to claim 12, the catheter has a proximal portion 30 and a distal portion 16, where the distal portion is more flexible than the proximal portion. Hence, the proximal portion is more crush proof. With respect to claim 50, the barrier is flush with the end of the catheter. Claims 63 and 65 are rejected in that the barrier is a compliant membrane. Claim 6 is rejected in that Pohndorf states that the pressure sensor may be of the type taught by Anderson 4407296, which is incorporated by reference. Anderson 440726 uses a piezoresistive pressure sensor. Hence, so does Pohndorf. Claims 67 and 68 are rejected for the reasons given above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 13-17, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Eigler et al 6328699. Pohndorf teaches in column 3, lines 19-27 that the pressure transducer is connected to an implanted monitor. Eigler et al further teaches that it is well known in such a system to have the monitor communicate wirelessly to an external device. Hence, it would have been obvious to modify Pohndorf et al to have the implanted monitor communicate wirelessly to an external device, as it is merely the substitution of a known communication method for another. The remaining features of claims 13-17 were discussed above in the anticipation rejection over Pohndorf. In addition, with respect to claims 48 and 49, the device of Pohndorf may be introduced transvenously (see column 5, line 12).

Claims 44 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674. With respect to claim 44, in column 8, lines 19-57, Brockway '674 teaches the equivalence of a coiled stabilizer like that of Pohndorf and a mesh stabilizer that promotes tissue in growth. As such, it would have been obvious to modify Pohndorf et al to use a mesh stabilizer, as it is merely the substitution of one known equivalent stabilizer for another. As such, the housing would

Art Unit: 3736

have a tissue in growth promoting surface, i.e. the one facing the direction of the coiled needle, and an in growth deterring surface, i.e. the remaining portion of the housing.

The device would be positioned as claimed in claim 44. With respect to claim 52, Brockway '674 teaches in column 12, line 37 to column 13 line 4, that it is known to provide a dissolvable material on the tip of a pressure transmission catheter, to ease the transluminal delivery of the pressure sensing device. Hence, it would have been obvious to modify Pohndorf to use a dissolvable material on the tip, to enable easier insertion of the device.

Claims 51 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 4846191. With respect to claim 51, in figure 4, Brockway teaches a barrier recessed from the end of a pressure transmission catheter. Hence, it would have been obvious to modify Pohndorf et al to use such a recessed barrier, as it is merely the substitution of one known functional equivalent catheter for another. Claim 64 is rejected in that the barrier of Brockway is a gel. Hence, it would have been obvious to modify Pohndorf to use a gel for the barrier, as it is merely the substitution of one known barrier for another.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf et al in view of Brockway et al 6409674 and Zheng 6662045. As discussed above, Brockway teaches alternative securing devices, so as barbs or mesh. Hence, it would have been obvious to modify Figure 7 of Pohndorf to use other fixation devices, as it is merely the substitution of one known equivalent device for another. In addition, Zheng teaches delivering a device into the heart wall, where an introducer sheath is

Art Unit: 3736

initially around the device, and then both the sheath and the device are advanced through the wall. Hence, it would have been obvious to modify the above combination to deliver the device using an introducer sheath, as it is merely the substitution of one known deliver device for another.

Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pohndorf in view of Sommer et al 6132456. Pohndorf teaches that the lead is introduced via any known way for introducing screw in leads for a pace maker. Sommer teaches such a method, where the lead is disposed at the distal end of an introducer sheath, and advanced to the insertion point, where it is screwed into the heart. Hence, it would have been obvious to modify Pohndorf to use such a delivery technique, as it is merely the use of a conventional delivery technique in the art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Porat et al 6277078 and Van Tassel et al 6645143 show devices to be placed in or through the heart.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

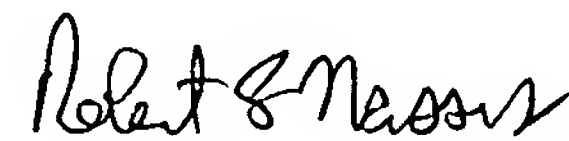
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
February 4, 2004



ROBERT L. NASSER
PRIMARY EXAMINER